Article

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Original article

Title: Characteristics of clinical measurements between biomechanical responders and non-responders to a shoe designed for knee osteoarthritis

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Abstract. [Purpose] The purpose of this study was to investigate the characteristics of biomechanical and clinical measurements in relation to the knee adduction moment when wearing a standard shoe and a shoe design for individuals with knee osteoarthritis (Flex-OA). [Methods] Kinematic and kinetic data were collected from thirty-two healthy individuals (64 knees) using a ten camera motion analysis system and four force plates. Subjects performed 5 walking trials under the two conditions and the magnitude of individuals' biomechanical responses where explored in relation to the clinical assessment of the Foot Posture Index, hip rotation range, strength of hip rotators, and active ankle-foot motion, all of which have been described as possible compensation mechanisms in knee osteoarthritis. [Results] Significant reductions in the first peak of the knee adduction moment (KAM) during stance phase (9.3%) were recorded ($p < 0.0001$). However, despite this difference, 22 of 64 knees showed either no change or an increased KAM, indicating a non-response or negative-response to the Flex-OA shoe. Significant differences were observed between the responder and non-responder subgroups in the hip rotation range ratio ($p = 0.044$) and the hip rotators strength ratio ($p = 0.028$). [Conclusion] Significant differences were seen in clinical assessments of hip rotation range and hip rotator strength between responders and non-responders using a cut-off of 0.02 Nm/kg change in the KAM.

Key words: Knee adduction moment, Hip rotation, Knee osteoarthritis

Introduction

Knee osteoarthritis (OA) is the most prevalent disease amongst individuals aged 50 years and older in South Korea, affecting approximately 12.5% [1]. Clinical characteristics of knee OA are: pain, decreased range of motion, joint instability, muscle weakness, joint stiffness, and proprioceptive loss, all of which decrease quality of life [2].

The knee adduction moment (KAM) during walking in patients with degenerative knee OA has been discussed in previous studies [3 – 6]. The KAM is primarily calculated by the ground reaction force and its lever arm. The KAM contributes to adduction of the knee and genu-varus deformities, which are significantly correlated with OA severity [7]. Therefore, reduction of the external KAM during walking is clinically important for treatment of OA. Biomechanical interventions such as: orthotic shoe inserts [8], knee braces [9, 10], and specialized footwear [11 – 14] for knee OA aim to improve pain, decrease joint loading, and delay disease progression.

Over the past two decades, specialized footwear has been developed for the potential conservative management of knee OA [12]. Recently, Shakoor et al. reported that, following use of specialized mobility footwear, the Flex-OA shoe, the KAM was reduced by 18% compared to use of the participants' own shoe [14]. Although the Flex-OA shoe had a significant effect on KAM, no study has explored whether this effect is universal or whether responder and non-responder groups may exhibit differences in clinical and biomechanical measurements. Therefore, the purpose of this study was to explore differences in KAM in a healthy population when wearing a standard shoe and the

Flex-OA shoe, and to investigate the characteristics of individuals' responses from biomechanical and clinical assessments.

METHODS

Participants

This study recruited 32 healthy volunteers who consented to participate in the study and met the selection criteria. There were twenty-four males and eight females in the study population. Participants were given a detailed explanation of the study procedure and written informed consent was obtained. This study was conducted in accordance with the principles of the Declaration of Helsinki and was approved by the STEMH Ethics Committee of the University of Central Lancashire (STEMH 347).

Volunteers who were able to walk freely for 10 m were recruited for this study. Volunteers who had any neurological, musculoskeletal, or cardiopulmonary problems were excluded. The mean age, height, and weight of all participants were 30.4 ± 11.5 years, 174.5 ± 9.6 cm, and 72.3 ± 12.9 kg, respectively.

Instrumentation and procedure

A Qualisys Motion Capture System (Qualisys, Gothenburg, Sweden) was used to collect three-dimensional kinematic and kinetic data from participants walking along a 10 m walkway wearing a

standard shoe (control) and the Flex-OA shoe. Qualisys Track Manager software (Qualisys, Gothenburg, Sweden) was used to obtain data using ten Oqus-7 cameras (Qualisys, Gothenburg, Sweden) sampling data at 100 Hz. The camera system was synchronised with four BP400600 force platforms (AMTI, Massachusetts, USA), which were embedded in the middle of the walkway and sampled data at 500 Hz. A 750 mm calibration wand was used to calibrate the motion capture system and an L-frame reference object was used to identify the lab origin.

Changes in joint angles and moments of 32 subjects (64 healthy knees) were measured during walking when wearing the Flex-OA shoe (DJO Global, Vista, CA, USA) and a standardised shoe (Athletic footwear, DJO Global, Vista, CA, USA), which were tested in a randomised order. For the dynamic walking conditions, participants wore 52 retro reflective markers (14 mm), which were attached bilaterally onto the: pelvis, thigh, leg, and shoes over the rearfoot, midfoot and forefoot. Additional markers were placed bilaterally over the following anatomical locations: malleoli, femur epicondyles, greater trochanters, and anterior and posterior superior iliac spines. Marker clusters of four markers were affixed bilaterally on the shank and thigh according to the six-degrees-of-freedom (6DOF) model [15] (Figure 1). Initially, a static trial was taken, which served as an anatomical calibration file. Participants were then asked to walk along a 10 m walkway in the laboratory at their self-selected walking speed. A total of 5 walking trials were collected for each shoe condition and data were obtained bilaterally. Participants were not given any walking instructions other than to walk at their self-selected speed and were allowed adequate rest if needed. In trials where participants did not

make complete foot contact on the force plate, kinetic data from that trial were excluded. The mean of all gait trials of the Flex-OA shoe and the standardised shoe of all participants were 7.4 ± 2.6 trials, and 7.2 ± 1.9 trials, respectively.

Following data collection, Visual 3D motion analysis software (C-Motion, Rockville, MD, USA) was used to analyse kinematic and kinetic data using the Calibrated Anatomical System Technique with a modified oxford foot model. Kinematic data were low-pass filtered with a 4^{th} order Butterworth filter with a cut-off frequency of 6 Hz. Kinetic data were low-pass filtered using a 4^{th} order Butterworth filter with a cut-off frequency of 15 Hz. KAMs were calculated using inverse dynamic analysis. Figure 2 illustrates examples of KAM during stance phase. The X-Y-Z Cardan sequence was used to define the order of rotations following the Right Hand Rule about the segment coordinate system axes. Joint kinematic and kinetic data were normalized to the gait cycle starting with initial heel contact. GRF data and joint moments were normalized for body weight.

The magnitude of individuals' responses where explored in relation to the clinical assessment of: the Foot Posture Index (FPI), passive hip rotation range, strength of hip rotators, and ankle motion, all of which have been described as possible compensation mechanisms in knee OA [16-18].

The FPI is a clinical diagnostic tool used to quantify the degree to which a foot can be considered to be in a pronated, supinated or neural position [19]. A previous study reported that the FPI exhibited good intra-observer reliability and moderate inter-observer reliability [20]. The six criteria version of the FPI was used to assess foot position on the bilateral foot. Foot position was

assessed while participants stood in their relaxed standing position with double limb support, arms along each side of the side of the body, and looking straight ahead. The six-items of the FPI were: talar head palpation, supra and infra malleolar curvature, calcaneal frontal plane position, prominence in the region of the talonavicular joint, congruence of the medial longitudinal arch, and abduction/ adduction of the forefoot on the rearfoot, with reference values ranging from -12 (severely supinated) to +12 (severely pronated).

A standard 12-in. plastic, round universal goniometer was used to measure passive hip rotation range of motion (ROM). For measuring hip ROM, participants were placed in the prone position on a firmly padded treatment plinth. The hip being measured was placed in 0° of abduction, the knee was flexed to 90° and the leg was passively moved to produce hip internal or external rotation. A mobilization strap was tightened over the sacrum to prevent pelvic movement. The investigator recorded the hip passive rotation ROM when a firm end-feel was noted. Three trials for each motion were performed with a rest period of approximately 1 minute between each trial. The mean value of the trials were used for statistical analysis. Previous studies have reported an intra-class correlation coefficient (ICC) of 0.94-0.99 for intra-rater reliability when this technique is used to measure hip rotation ROM [21].

Strength (force) measures were obtained for left and right hip internal rotation (IR) and external rotation (ER) muscles. The maximum isometric muscle strength (peak force) of the participants' hip rotators was assessed using the Lafayette dynamometer (Lafayette Instrument

Company, Lafayette, IN, USA) with standardised manual muscle testing procedures [22] and dynamometer placements [23]. The assessment position of the hip rotator strength was similar to the hip rotation ROM measurement procedure. The contact point for the Lafayette dynamometer was 2.5 cm proximal to the medial and lateral malleolli. The participant was asked to ‘‘push″ into the padded Lafeyette dynamometer for duration of 5 seconds as hard as they could. Three trials for each strength test were performed with a rest period of approximately 2 minutes between each trial. The mean value of the trials were used for statistical analysis. An ICC for intra-rater reliability using this technique for hip rotator strength assessment, has previously been reported as 0.91-0.96 [21].

An Ankle Foot Motion Test (AFMT) was conducted to measure active maximum rearfoot inversion and eversion range. The subjects were asked stand in a neutral foot position and then invert and evert both feet simultaneously. Twenty-six retro reflective markers were placed bilaterally on the: malleoli, rearfoot, midfoot, and forefoot to analyse the AFMT. For calibration purposes, data were captured for 1 second when the participant stood with their feet shoulder-width apart. The difference between the maximum inversion and eversion ROM of the rearfoot to tibial during AFMT trials was calculated. The mean values for three test trials were used for statistical analysis.

Data analysis

Data were found to be suitable for parametric testing. A two factor repeated measures ANOVA

with Bonferroni′s correction was used to determine the effect of shoe condition and knee side in stance phase during walking. The magnitude of change in first peak KAM was then used to predict responders and non-responders subgroups. The number of responders was twenty-one subjects (42 knees bilaterally) and the non-responders was eleven (22 knees bilaterally). Differences between the responders and non-responders subgroups for the clinical and biomechanical measurements were analysed using independent t-test and Mann-Whitney U test. Statistical analyses were conducted using SPSS version 23.0. Statistical differences were defined as significant at the $\alpha = 0.05$ level.

The authors could not find data specific to the minimally clinically important change in KAM. However, significant differences in KAM have been shown in conservative interventions of Knee OA with changes as low as a 0.02 Nm/kg [24]. In addition, changes of 7% in KAM have resulted in a 23% improvement in KOOS score [25], which is greater than the 10% threshold suggested to be clinically important by Roos and Lohmander [26]. Therefore, a pragmatic threshold of a clinically important reduction of 0.02 Nm/kg, equating to a 5% change was used in this exploratory study.

Results

The mean of walking speed in both the Flex-OA shoe and the standardised shoe of all participants were 1.435 ± 0.126 m/s, and 1.433 ± 0.142 m/s, respectively and there was no significant difference in walking speed between shoe conditions ($p = 0.811$). Significant differences were observed in the KAMs between conditions and knee sides in various stance phases (Table 1). The first

peak of the KAM during loading (0 - 25% of stance phase) showed that the Flex-OA shoe condition significantly decreased KAM for both knees ($p = 0.00008$) (Tables 1 and 2). In addition, there were significant differences in the KAM between shoe conditions and knee sides at mid stance ($p = 0.017$) (Tables 1 and 2). On the right side, the second peak KAM was significantly decreased during late stance phase ($p = 0.001$) (Tables 1 and 2). However, there were no interaction effects between shoe conditions and knee sides in any of the KAM values ($p > 0.05$) (Table 2).

Despite a significant 9.3% reduction in the first peak (loading) KAM when wearing the Flex-OA shoe ($F = 26.018$, $p = 0.00008$) (Table 2), 22 of the 64 knees showed a response of either an increased KAM or no change using a threshold of 0.02 Nm/kg, equating to a 5% change, indicating a non-response (Figure 3). Therefore, the change in KAM between the Flex-OA and the standardised shoe condition was used to separate the data into two subgroups (42 responders and 22 non-responders) (Table 3). These subgroups were then used to explore whether any differences existed in the clinical measures. Independent t-tests and Mann-Whitney U tests showed significant differences between responders and non-responders in hip IR/ER rotation ($p = 0.044$)and hip IR/ER strength ratio ($p = 0.028$) (Table 3). However, there were no significant differences in the FPI, hip internal rotation range, hip rotators strength, and all AFMT between subgroups ($p > 0.05$) (Table 3).

Discussion

We observed that, in 32 subjects, 22 of 64 healthy knees, experienced negative or minimal effect on KAM during walking when wearing the Flex-OA shoe. Therefore, this study examined whether clinical and biomechanical measurements could distinguish between KAM response/ non-response subgroups in healthy individuals.

The clinical and biomechanical measurements used in the study were directly related to the coronal and transverse planes, which are arguably the most important considerations for individuals with knee OA. The results of this study showed that the ratio of hip IR/ER range and the ratio of hip IR/ER strength exhibited significant differences between responders and non-responders subgroups ($p < 0.05$). Although interventions such as the Flex-OA shoe and lateral wedging have shown considerable, clinically important effects on the KAM in previous studies [11 – 14], hip rotation ranges and strengths may also be important factors which could influence the first peak of the KAM during walking. In this study, the responders subgroup showed a greater value for hip ER ROM (53.0°) than hip IR (41.2°). On the other hand, the non-responders subgroup showed greater hip ER ROM (41.2°) than IR (43.7°). Therefore, the IR/ER ratio of the hip rotation range was significantly different between subgroups ($p = 0.044$), with the responders having an IR/ER ratio ≤ 1, whereas the non-responders' ratio was ≥ 1. Studies performed on healthy subjects have consistently shown that the bilateral hip IR/ER rotation is consistently equal and have reported little difference between IR and ER of the hip, with differences ranging from as little as 1 to 5 degrees [27 -29]. Previous studies have suggested that a greater difference between hip IR and ER range, is linked to a more "abnormal"

alignment of the lower extremity including: tibial torsion, genu valgum, genu varum, pes equinus, pes planus, and metatarsus varus [30 – 33]. It has also been reported that individuals with a lower extremity movement impairment syndrome are usually characterised by increased hip IR, increased knee valgus, and excessive foot pronation [34, 35]. On the other hand, increased knee varus alignment has been associated with a greater risk of medial knee OA progression [36]. From a biomechanical perspective, the increased KAM is directly linked to the knee varus alignment which, in turn, contributes knee OA progression [37, 38]. Therefore, responders to the Flex-OA shoe exhibit characteristics that can be more closely linked with knee OA progression, namely the hip IR/RE ratio, than those of non-responders.

Although individually hip IR and ER strength exhibited no significant difference between responders and non-responders subgroups ($p > 0.05$), the hip IR/ER strength ratio showed a significant difference between subgroups ($p = 0.028$), indicating a difference in the balance of IR/ER strength. These results were similar to those of hip IR/ER ROM assessments, indicating a possible link between hip rotators strength and hip rotation ROM. Cibulka et al [21] showed evidence that greater hip ER range compared to IR range may contribute to weakness of hip internal rotator muscles, whereas those with greater hip IR range often exhibit weakness of the hip external rotator muscles.

In this study, the FPI and AFMT were used to measure static ankle-foot alignments and dynamic motions and showed no significant differences in all variables investigated. To the authors' knowledge, no studies have investigated the difference in FPI score and active ankle-foot movement

range between two subgroups. However, a previous study identified normative values for differences in FPI scores across feet by providing cut-off limits between normal difference and asymmetrical differences [39]. This study reported that a normal reference range between ±1 SD from the mean was -2 to +2. In the current study, mean FPI score of two subgroups ranged between 2.16 to 2.89. As most of the participants had normal ankle-feet alignment, there were no significant differences in FPI score and AFMT evaluation between responders and non-responders subgroups. However, these may be important measures in other clinical presentations of knee OA.

This was an exploratory study conducted on healthy individuals, who were mostly younger than the general age range of those suffering from knee OA. The purpose was to determine if biomechanical response to footwear can be predicted from clinical assessment, however as this was performed on healthy individuals there is a limitation to generalize these results to individuals with knee OA. Further exploration of different clinical assessment scores, including the ones identified in this study, is therefore required in patients with knee OA. Such assessments (i.e. Q angle, knee varus angle, Craig's test) may be suitable as clinical predictors for responders and non-responders to footwear interventions. More work is required to explore if subgroups exist in patients with knee OA, and if so, optimal cut-off thresholds for the different clinical measures should be investigated. This information would improve our understanding of the effectiveness of different conservative interventions and would assist with identification of relevant interventions for the different subgroups.

Conflict of interest statement

We can confirm that there is no conflict of interests for any of the authors.

Table Legends

Table 1. Mean values of coronal plane knee moments in stance phase (N=32)

Table 2. Repeated measure ANOVA comparing coronal plane knee moments under the shoe conditions and knee sides in stance phase during walking (N=32)

Table 3. Mean values of clinical and biomechanical assessments and t-tests between responders and non-responders

Figure Legends

Figure 1. Marker positions on lower limbs and pelvic during static calibration and walking trials.

Figure 2. Intra-individual variability of knee adduction moment during stance phase. Flex-OA shoe moment (solid line) and standardized shoe moment (dot line) from 25 repetitive trials (thin line) and their average (thick lines).

Figure 3. Biomechanical responders/non-responders to the Flex-OA shoe defined by a threshold of a 0.02 Nm/kg change in knee adduction moment (KAM).

Table 1. Mean values of coronal plane knee moments in stance phase (N=32)

	Shoe conditions	Knee sides	Mean±SD
Knee adduction moment 1st peak 0-25% stance (Nm/kg)	Flex-OA	Right	-0.413±0.143
		Left	-0.427±0.121
	Standardized	Right	-0.456±0.143
		Left	-0.472±0.123
Knee adduction moment at mid stance 25-75% stance (Nm/kg)	Flex-OA	Right	-0.136±0.082
		Left	-0.199±0.101
	Standardized	Right	-0.152±0.072
		Left	-0.204±0.106
Knee adduction moment 2nd peak 75-100% stance (Nm/kg)	Flex-OA	Right	-0.323±0.117
		Left	-0.371±0.118
	Standardized	Right	-0.319±0.108
		Left	-0.379±0.116

Table 2. Repeated measure ANOVA comparing coronal plane knee moments under the shoe conditions and knee sides in stance phase during walking (N=32)

Moment values	Level	F	p
Knee adduction moment 1st peak 0-25% stance (Nm/kg)	Shoe conditions	26.018	0.000
	Knee sides	0.522	0.477
	Conditions*sides	0.063	0.804
Knee adduction moment at mid stance 25-75% stance (Nm/kg)	Shoe conditions	6.488	0.017
	Knee sides	13.479	0.001
	Conditions*sides	1.508	0.231
Knee adduction moment 2nd peak 75-100% stance (Nm/kg)	Shoe conditions	0.135	0.716
	Knee sides	5.853	0.023
	Conditions*sides	0.956	0.338

Table 3. Mean values of clinical and biomechanical assessments and t-tests between responders and non-responders

	Responders (n_1=42)	Non-responders (n_2=22)	P
Different KAM (Nm/Kg)	0.08±0.06	-0.03±0.05	**<0.001**
FPI (score)	2.16±2.48	2.89±3.26	0.661
Hip rotation range			
Internal rotation (degree)	41.21±12.97	43.72±14.54	0.526
External rotation (degree)	52.95±11.50	41.16±13.46	**0.002**
Ratio	0.86±0.51	1.21±0.70	**0.044**
Hip rotators strength			
Internal rotators (kgf)	7.94±2.73	8.95±2.55	0.197
External rotators (kgf)	10.05±3.55	9.71±2.85	0.731
Ratio	0.81±0.19	0.97±0.30	**0.028**
AFMT rearfoot			
Coronal motion (degree)	29.05±7.63	29.60±7.73	0.804
Transverse motion (degree)	22.84±7.14	24.14±6.28	0.514
Ratio	1.43±0.81	1.31±0.49	0.581
AFMT midfoot			
Coronal motion (degree)	5.70±2.45	6.11±2.46	0.565

Transverse motion (degree)	13.43±5.25	14.23±4.68	0.584
Ratio	0.45±0.17	0.45±0.19	0.963

KAM differential means different knee adduction moment value between OA-Flex and standardized shoe condition. KAM = Knee Adduction Moment, FPI = Foot Posture Index, IR = Internal Rotation, ER = External Rotation, AFMT = Ankle Foot Motion Test

Figure 1. Marker positions on lower limbs and pelvic during static calibration and walking trials.

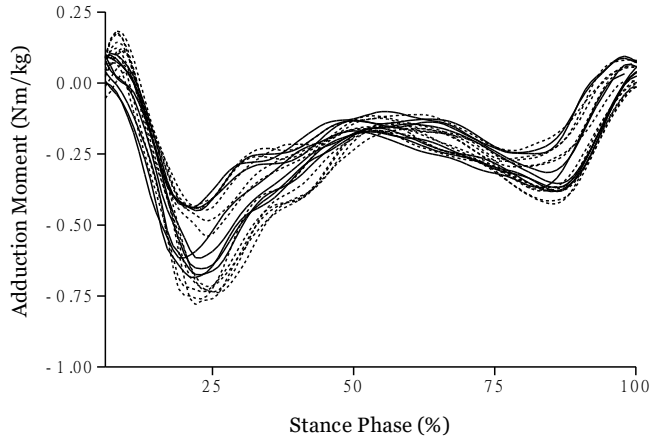

Figure 2. Intra-individual variability of knee adduction moment during stance phase. Flex-OA shoe moment (solid line) and standardized shoe moment (dot line) from 25 repetitive trials (thin line) and their average (thick lines).

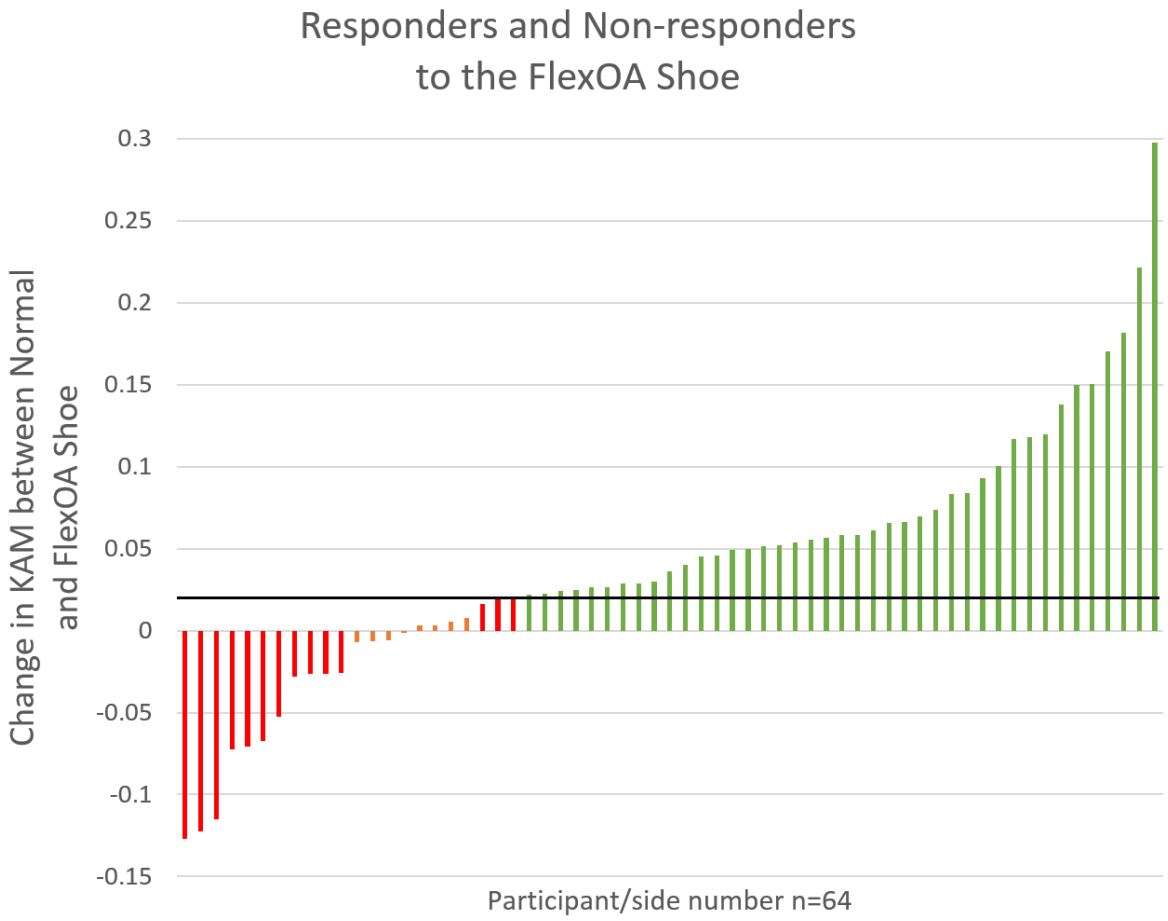

Figure 3. Biomechanical responders/non-responders to the Flex-OA shoe defined by a threshold of a 0.02 Nm/kg change in knee adduction moment (KAM).

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